# NOTICE OF PROGRAM INTEREST

## EXPLORATORY/DEVELOPMENTAL PROGRAMS FOR USES OF ISOTOPES IN MEDICINE

## DE-PS01-00NE22740

Office of Isotope Programs
Office of Nuclear Energy, Science and Technology
United States Department of Energy

### PURPOSE

In accordance with 10 CFR Part 600.9, the Department of Energy (the Department), Office of Isotope Programs solicits responses to this Notice of Program Interest (NOPI) for research and development programs for new and innovative uses of isotopes, including alpha emitting isotopes in the diagnosis and therapy of cancer, HIV and other infectious diseases or other innovative medical applications. The diagnosis and therapy of many diseases with the use of isotopes will be the subject of a high risk/high impact research program the Department calls the Advanced Nuclear Medicine Initiative (ANMI). The Department wishes to encourage research in these areas by providing resources for the required research. This program is not intended to support human clinical trials.

Researchers with innovative ideas in the use of isotopes for diagnosis and therapy of many diseases have had difficulty obtaining funding for areas of research that are not closely tied to specific isotopes, means of delivery and disease. The purpose of the ANMI is to support broad-based research on new uses of isotopes, including alpha emitters, for the diagnosis and therapy of life threatening diseases or other innovative medical applications. The Department is looking for applications in these areas with the view toward providing funding or the required isotopes as part of a research program.

### ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic United States commercial and nonprofit organizations, public and private, such as universities, colleges, hospitals, laboratories, and units of State and local governments. The DOE National Laboratories are specifically included in this solicitation. Partnering arrangements among these entities are encouraged. In addition, the Department encourages the participation of non-U.S. entities as minority partners in submissions. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to respond as principal investigators.

### MECHANISM OF SUPPORT

The Department's ANMI financial assistance awards will be funded through grants and/or cooperative agreements. Requests may be made for up to three years support and up to $250,000 per annum in direct costs or for isotopes valued up to $250,000. The purchase of equipment (more than $5,000 or more than one year of useful life) and supplies will be acceptable based on reasonableness and contribution to the project. Applications will be subject to peer review by the Department's Nuclear Energy Research Advisory Committee. Members of the committee that participate in a submission or whose institutions submit a proposal must resolve conflict-of-interest concerns. Awards may be renewed upon submittal of an application prior to the original end date. Awards will be administered under the policies of the Department. All isotopes used in the funded research must be purchased from the Department, produced in the recipient facility or otherwise obtained domestically and exclusively for this purpose.

### RESEARCH OBJECTIVES

Research topics to be supported will be those falling within broad areas of clear importance in the use of isotopes, including alpha emitters, in diagnostics and therapy of cancer and other infectious and/or debilitating diseases.

1. Development of new and innovative uses for isotopes for diagnostics of debilitating and infectious diseases.

2. Development of new and innovative uses for isotopes, including alpha emitters, for the therapy of infectious and debilitating diseases.

3. Development of new and innovative chemicals, such as monoclonal antibodies, peptides, fragments etc . . . , that will seek out and attach themselves to diseased cells, whether they are cancerous, HIV infected, or other.

4. Development of new and innovative chemicals, such as chelators, that will bind isotopes to the chemicals that attach themselves to diseased cells.

5. Development of new and innovative applications of 1-4 above to apply to other medical applications.

6. Development of new and innovative isotope production methods, or improvements thereof, for isotopes to be used in medical applications.

CONTENTS OF AN APPLICATION

Applications should present a general scope-of-work, the scientific significance of the proposed work, a statement of objectives, the rationale for selecting the proposed approach to achieve the objectives, the qualifications of the principal investigator and the applicant organization, and the amount of funding, or isotope, required. Since individual applications will compete with others on related topics, it should present the scientific merit of the proposed project clearly and convincingly and should be prepared with the care and thoroughness of a paper being submitted for publication.

Elaborate presentations are not desired. Do not include, in the body of the application, documents that will not reproduce. If needed, an appendix is acceptable. Only one electronic copy is required with an appendix (if necessary) is required (not to exceed 50 pages). The following is a list of essential items that an application must contain.

1. The Face Page (SF 424): Completed and signed (electronically) by authorized officials

2. Cost Proposal (Budget Pages)(SF-424C): Show amounts in U.S. dollars, with supporting written justification sufficient to evaluate the costs of the proposed project.

3. Application Summary Page: Containing a brief abstract of the scope-of-work, and response to ANMI questions. No proprietary information should be on this page.

4. Application Description: A detailed description of the Application, including the objectives and the plan for carrying it out. This section is limited to a length of 10 double-spaced pages, and must include a one page summary containing a brief statement of objectives for each task and indicate the starting date, duration and overall cost of each task.

5. Bibliography: Containing literature citations from the description section.

6. Contact and biographical information: about the background and experience of the principal investigator(s) including references to publications.

7. Facilities and Resources: Brief information on the experience of the submitting organization, its facilities and resources.

8. Current and Pending Support: A summary of all current and pending support for all similar and related projects. Also, a brief description of support for all projects which involve the principal investigator(s) and the time they will commit to each.

9. Required Pre-Award Forms in addition to the above forms are:
   (a) Assurance of Compliance Form (DOE F 1600.5)
   (b) Simpson-Craig Amendment Representation
   (c) Notice of Energy R&D Project (DOE F 1430.22)
   (d) Restrictions on Lobbying
   (e) Certification for A Drug Free Workplace

COPIES OF ALL NECESSARY FORMS ARE AVAILABLE ON THE WORLD WIDE WEB AT THIS ADDRESS: http://www.ne.doe.gov

10. DOE is under no obligation to pay for any costs associated with the preparation or submission of applications if an award is not made.

11. Doe reserves the right to fund, in whole or in part, any, all, or none of the applications submitted in response to this solicitation.

SPECIFIC INSTRUCTIONS

Consistent with the Federal Register notice of December 10, 1999, the solicitation is available through the *Industry Interactive Procurement System (IIPS) at* http://doe-iips.pr.doe.gov. Dissemination of the solicitation, receipt of applications, evaluations, and the notice of financial assistance will occur in a paperless environment. Prospective applicants are responsible for checking the IIPS web site at regular intervals for updates since any additional changes or amendments to the solicitation will only be posted on the web. You may subscribe to receive notification of updates via IIPS; however, the Department does not guarantee notification will be made.

Prospective applicants with questions pertaining to the contents of the solicitation or the operation of IIPS are urged to transmit these questions via e-mail to the addresses provided in the section entitled "Inquiries". Applicants are required to register with IIPS and are strongly encouraged to do so as soon as possible prior to the application deadline. Refer to the NOPI Guide and the IIPS Internet Web site for instructions http://doe-iips.pr.doe.gov .

The deadline for receipt of applications is: Close of Business, 2:00 P.M., Washington, D.C., January 28, 2000.

**ALL APPLICATIONS MUST HAVE AN IIPS TRANSMISSION TIME STAMP OF NOT LATER THAN 2:00 P.M. EASTERN STANDARD TIME**.

REVIEW CONSIDERATIONS

Applications will be reviewed by DOE staff for broad conformance to the objectives of this APPLICATION. The selected applications will then be submitted for peer-review to the Nuclear Energy Research Advisory Committee. As part of the peer-review the committee will determine whether the applications are competitive or noncompetitive based on their scientific merit relative to other applications received in response to this solicitation. Applications deemed to be competitive will be discussed and assigned a priority score. Applications determined to be noncompetitive will be withdrawn from further consideration and the Principal Investigator and the official signing for the submitting organization will be notified.

EVALUATION CRITERIA

The goals of the ANMI are to advance the creative use of isotopes, including alpha emitters, in the diagnosis and therapy of cancer, other highly infectious diseases such as HIV and other debilitating diseases, for example, rheumatoid arthritis and other innovative medical applications. In the review, comments on the following aspects of the application will be made in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. The relative importance of each of these criteria will be considered equally and addressed.

1. Significance. Does this study address an important problem with the potential of leading to new and innovative applications of isotopes, including alpha emitters, in the diagnosis or therapy of the target diseases? If the goals of the application are achieved, how will scientific knowledge be advanced? What will the effect of these studies be on the concepts or methods that drive this field?

2. Approach. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate for the testing of the approach within the time and funding constraints? Does the applicant acknowledge potential problem areas and consider alternatives?

3. Innovation. Does the approach employ novel concepts or isotopes, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

4. Investigators. Are the qualifications and research experience of the Principal Investigator and staff appropriate for the proposed research?

5. Laboratory Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed research take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

The peer review committee will also examine the provisions for the protection of animal subjects and the safety of the research environment.

AWARD CRITERIA

Each application will compete with every other approved application for available funds. The following will be considered in making funding decisions: Quality of the proposed project as determined by the committee, availability of funds, and program priority.

INQUIRIES

Inquiries are encouraged. The opportunity to clarify any issues or questions from potential respondents is welcome.

Direct inquiries regarding programmatic issues to:

Mr. John Pantaleo
Office of Isotope Programs, NE-70
Office of Nuclear Energy, Science and Technology
19901 Germantown Road
Germantown, MD 20874
Telephone: (301)903-2525
FAX: (301)903-5434
Email: john.pantaleo@hq.doe.gov

Direct inquiries regarding contractual issues to:

Mr. Richard G. Lewis
Contracting Officer (MA-542)
U. S. Department of Energy
1000 Independence Ave., SW
Washington, D.C. 20585
Telephone: (202)426-0066
FAX: (202)426-0178
Email: richard.lewis@pr.doe.gov

Direct inquires regarding IIPS issues to:

IIPS Administrator
Telephone: 800-683-0751
Email:IIPS-Administrator@hq.doe.gov

All responses to questions received will be published on the NE Home Page. Therefore, the deadline for submitting inquiries is Close of Business, Washington, D.C., January 12, 2000. No responses will be provided after this date and prior to the application receipt deadline of 2:00 P.M. (EST), January 28, 2000.

Signed in Washington DC, Dec. 8, 1999
William D. Magwood, IV, Director
Office of Nuclear Energy, Science
and Technology

PCDOCS#65901